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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,068	10/30/2000	Martin E. Davis	835-005.003	8317

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EXAMINER
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MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/02/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicant No.</b>	<b>Applicant(s)</b>
	09/702,068	DAVIS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Michael V. Meller	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 April 2002.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3 and 5-15 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3 and 5-15 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The range of 5.5 to 20% degree of hydrolysis finds no support in the instant specification. Applicants do have support for 5.5-6.5 % , 11.0-12.5 % and 19.5-20.5 %, but not for 5.5-20%. Simply because applicants have taught isolated ranges of degrees of hydrolysis, does not enable the invention for such a broad range as 5.5-20%.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 are confusing since “comprising trypsin” is not understood. Either the proteolytic enzyme is trypsin or some mixture of enzymes, a enzyme cannot comprise a specific one, it is a specific one. It may be clearer for applicants to simply claim trypsin with the recitation of “proteolytic enzyme”.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-3 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 4-82898 (abstract-JP) in view of Hawley's Condensed Chemical Dictionary (Hawley).

Applicant first argues that JP teaches a more complex process than their invention. They argue that JP further centrifugates, dries, rehydrates, purifies. While this is interesting, JP still reads on applicants claims. JP does do further purification and other techniques but JP does perform the claimed process.

While JP does not use trypsin as applicants point out, it would have been obvious to use trypsin since trypsin is well known as a common alternative to other proteases such as pepsin which JP does use in their process, see Hawley. Thus it clearly would have been within the purview of the skilled artisan in an effort to optimize the results and simply the artisan's choice to use trypsin instead of pepsin.

Applicants next argue that only 1200 micrograms of ACE inhibiting powder were recovered in JP from 5 grams of whey starting material, but it is also noted that 4 grams of peptide mixture was obtained from the process as well and the only reason that further purification and other techniques were used in addition to the steps taught by JP that applicants also claim (as noted above) was to confirm the sequence and activity of the protein obtained. Thus, in fact, 4 grams of the ACE inhibitor were obtained in JP.

Dr. Rao's declaration have been considered but there are two major problems with it, first, it is not signed and second, it compares a reference which was not even applied in the last Office action. While applicant may feel JP 04282400 may be more appropriate as a piece of prior art, this reference was not applied against the instant claims and thus the declaration carries no weight with this rejection.

The new claims which incorporate the characteristics of the hydrolyzate are deemed to be inherent characteristics to the ACE inhibitor yielded by the process of JP. The fact that the claims may use a whey protein isolate which was produced by ion exchange does not change the type of isolate used and if so, it would have been obvious to use such well known column chromatography to yield such a protein isolate. Further, to yield a protein isolate which has a protein content of at least 94 % and an ash content of less than 3% is inherent to the whey protein isolate used or is in the very least obvious to yield since using column chromatography such as ion exchange is well known in the art and commonly used by one of ordinary skill in the art to purify proteins.

The degree of hydrolysis is also an obvious limitation since one would want to stop the reaction at a reasonable time as noted by JP. JP does not mention degree of

hydrolysis so it is assumed that the degree of hydrolysis would be the same for JP as the invention or in the very least obvious to do it at the degree of hydrolysis as claimed since applicants want to optimize their results and such modifications and optimizations would be simply the choice of the artisan in an effort to yield the most effective results.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller  
Examiner  
Art Unit 1651

MVM  
June 27, 2002